

REMARKS

Claims 1 and 22, and their respective progeny stand rejected under 35 USC 101 as claiming the same subject matter already claimed in *Nadol I*¹ and/or *Nadol II*² (collectively referred to herein as “*Nadol*”). These claims also stand rejected as claiming an obvious variation of what is already claimed by *Nadol*.

Applicant's claim 1 recites a pliant membrane made of a material selected to form a balloon having a specified acoustic impedance. In particular, claim 1 recites a pliant membrane “selected to form a balloon having an acoustic impedance low enough to permit said eardrum to respond to incident acoustic waves”. Similarly, claim 22, recites a surgical method that includes positioning a balloon having the foregoing impedance properties.

In contrast, the claims in *Nadol* do not recite any limitation on the acoustic impedance of the balloon formed by the pliant membrane. Moreover, a limitation on the acoustic impedance of the balloon is not an obvious variation of what is claimed in or taught by *Nadol*.

Nadol teaches a middle-ear prosthesis having a balloon that is capable of flexing in response to incident sound waves.³ However, *Nadol* does not disclose what the flexibility of the balloon should be. Instead, *Nadol* speculates that “a flexible compressible object with a thin balloon membrane should improve hearing” but that the amount of flexibility is unknown, difficult to quantify, and must be ultimately be determined by clinical observation.⁴

Applicant has found that a prosthesis constructed according to the *Nadol* specification does not significantly improve hearing. In the course of further experiments, Applicant discovered that the effectiveness of the balloon does not depend solely on the flexibility of the balloon membrane, as suggested by *Nadol*. Instead, Applicant discovered that the effectiveness of the balloon depends on its acoustic impedance, a concept never discussed or alluded to in *Nadol*.

Applicant has condensed the various factors that affect impedance into an “equivalent

¹ *Nadol, Jr.*, U.S. Patent No. 5,356,430 for “Hearing Prosthesis”, issued October 18, 1994.

² *Nadol, Jr.*, U.S. Patent No. 5,480,433 for “Method of Treating Hearing Loss”, issued January 2, 1996.

³ *Nadol*, col. 3, lines 6-7 (“The balloons must be able to flex with both pressure changes and sound vibrations”).

⁴ *Nadol*, col. 4, lines 11-21.

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volume", as defined on pages 7-8 of the specification. This quantity is amenable to measurement outside the patient. As a result, the performance of a balloon *in situ* can be now be predicted without the extensive clinical observation.

All of Applicant's claims include a limitation on the acoustic impedance of the balloon. This limitation does not appear in any *Nadol* claim. Nor is this limitation suggested by any teaching in *Nadol*. Applicant and Nadol therefore claim different inventions. Accordingly, Applicant requests withdrawal of the rejection of independent claims 1 and 22, and all claims dependent thereon.

No additional fees are believed to be due in connection with the filing of this response. However, to the extent that additional fees are due, or if a credit is forthcoming, please adjust our Deposit Account No. 06-1050.

Respectfully submitted,

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